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SUBMITTED ELECTRONICALLY

Marilyn Tavenner
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8011
Baltimore, MD 21244–1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015

Dear Administrator Tavenner:

On behalf of Pfizer Inc. (Pfizer), I am pleased to submit comments on the calendar year (CY) 2014 Medicare Physician Fee Schedule (MPFS) proposed rule, published in the *Federal Register* on July 11, 2014.

Our comments address the following topics:

1. **Support for Proposed Changes to the Primary Care and Care Coordination Incentives**
   Pfizer supports CMS' proposal to create one new G-code to describe and allow payment for physicians providing chronic care management (CCM).

2. **Support for CMMI Data Submission Requirements**
   Pfizer is supportive of CMS' proposal mandating all Center for Medicare & Medicaid Innovation (CMMI) demonstration participants compile and submit patient-specific health information to CMS.

3. **Do Not Support Proposal to Refine Local Coverage Determination (LCD) Process for Clinical Diagnostic Laboratory Tests**
   Pfizer strongly encourages CMS to reconsider this proposal to maintain public input and process transparency.

4. **Do not support proposed revisions regarding Sunshine Act regulations**
   Pfizer agrees with CMS that clear implementation guidance regarding the Sunshine Act's treatment of continuing medical education is important ("Sunshine Act regulation").[1] Pfizer respectfully disagrees with CMS' proposed revisions, however, and asks CMS not to implement its proposed changes.

5. **Changes to Measure Sets and Suggested Areas for Inclusion in the Physician Quality Reporting System (PQRS) Related to Quality Measures**
   Pfizer:
   - *Strongly supports CMS' inclusion of the measure "Tobacco Use and Help With Quitting Among Adolescents" in the PQRS measure set;*
   - *Supports CMS' proposed removal of the measures "Back Pain: Initial Visit" and "Back Pain: Physical Exam" from the PQRS measure set and inclusion of the measure "Median Time to Pain Management for Long Bone Fracture" and encourages CMS to consider additional pain assessment measures in PQRS;*
   - *Supports CMS' inclusion of the measures "Lung Cancer Reporting (Biopsy/Cytology Specimens)," "Lung Cancer: Reporting (Resection Specimens)," and "Melanoma Reporting."*
   - *Encourages CMS to refrain from removing topped out measures such as "Urinary Incontinence: Characterization of Urinary Incontinence in Woman Aged 65 years and Older" from pay-for-reporting programs and encourage CMS to consider additional measures assessing care for urinary incontinence for PQRS.*
   - *Encourages CMS to assume stewardship responsibilities for chronic obstructive pulmonary disease (COPD) measures proposed for removal or identify a measure contractor for ongoing measure maintenance, at least until such time as appropriate replacement measures can be identified.*
   - *Encourages CMS to postpone removal of the stroke rehabilitation measures until it can be determined whether they will remain in the inpatient setting through the Inpatient Quality Reporting (IQR) program.*
   - *Encourages CMS to consider additional measures assessing the care of patients with venous thromboembolism (VTE) to replace measures proposed for retirement.*

6. **Establishment of New Cross-Cutting Individual Measures**
   Pfizer strongly supports CMS' decision to establish a list of individual cross-cutting measures and requirements for provider reporting.

7. **Expansion of the Value-Based Payment Modifier (VBPM)**
   Pfizer supports CMS' proposals related to the continued expansion of the VBPM to include more providers and provider types in favor of both quality and cost goals. However, regarding the Medicare Spending per Beneficiary and Total Per Capita Cost measures, we are concerned that, in an effort to stem costs, the application of unbalanced cost measures could result in reduced provision of needed care and decreased beneficiary access to medically beneficial treatments, especially when applied in an incentive program. Therefore, we encourage CMS to investigate alternative frameworks for true efficiency measurement that would allow for the proper balanced evaluation of cost and quality.

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[1] The Sunshine Act regulation is at 42 C.F.R. § 403.900-.914.

8. **Proposed Quality Measure Changes to the Medicare Shared Savings Program (MSSP)**
   Pfizer:
   - *Supports CMS' proposal to add the measure "All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (addition)."*
   - *Encourages CMS to reconsider the removal of the measure "Diabetes Mellitus: Tobacco Non Use."*
   - *Suggests CMS consider the following measurement gaps: medication adherence, pain, and bladder control.*

Detailed comments on each of the above can be found on the following pages.

1. Support for Proposed Changes to the Primary Care and Care Coordination Incentives

In the final rule for CY 2014, CMS adopted a new G-code to describe provision of complex CCM services under certain circumstances. In this year's Proposed Rule, CMS proposes new Relative Value Units (RVUs) for the G-code and refines the scope of and restrictions on billing for CCM services under it. The Proposed Rule also would add to the existing scope of service requirements a requirement that CCM services must be furnished with the use of certified electronic health record technology and an electronic care plan accessible to all providers in the practice.

Pfizer supports CMS' proposal to create one new G-code to describe and allow payment for physicians providing chronic care management. The creation of these codes demonstrates CMS' continued emphasis on efforts to promote effective care coordination. Care coordination remains an important component of patient care, particularly for individuals with multiple chronic conditions. These codes recognize the critical activities undertaken by both primary care and specialty providers in treating these patients.

For example, oncology is an area where these codes may recognize and reimburse physicians for providing additional services to better manage patients' care. Oncologists often provide specialty care in treating a patient's cancer while also coordinating services and treatments the patient is receiving for associated comorbidities or other chronic conditions. While the oncologist is not technically the patient's primary care physician, they may be performing services not typically considered to be associated with their specialty.

We further support CMS' proposed inclusion of a new scope of service requirement for electronic care planning capabilities and electronic health records, because we believe this will help ensure access to CCM services 24 hours a day, seven days a week, as well as facilitate the requisite communication among healthcare professionals treating the patient.

2. Support for CMMI Data Submission Requirements

CMMI evaluations typically include questions related to clinical quality, patient experience, and utilization and expenditures. In the proposed rule, CMMI cites the need for individually identified data to account for differences between control and model groups and to ensure the models' results meet a high standard of evidence. Based on this, CMMI believes it requires access to patient records that are not generally available to the agency to evaluate its models, and proposes to require model participants, providers and suppliers working under CMMI models to submit individually identifiable health information. To the extent that the goal of a CMMI model is to engage private payers, this data would include the individually identifiable information for patients in commercial health plans in addition to Medicare and Medicaid beneficiaries. The proposed regulation will provide legal authority for HIPAA Covered Entities to disclose required protected health information.

Pfizer is supportive of CMS' proposal mandating all Center for Medicare & Medicaid Innovation demonstration participants compile and submit patient-specific health information to CMS. Pfizer supports efforts to increase data availability and access and encourages CMS to make these data publicly available. Allowing external researchers access to these types of (aggregated, de-identified) data can help address gaps in evidence about the use of healthcare products and services in real-world settings.

3. Do Not Support Proposal to Refine Local Coverage Determination (LCD) Process

In the Proposed Rule, CMS notes that section 216 of the Protecting Access to Medicare Act (PAMA) requires all coverage policies for clinical diagnostic laboratory tests to be made "in accordance with the process for making a local coverage determination." Accordingly, CMS proposes to establish a specific process that Medicare Administrative Contractors (MACs) must follow when developing clinical diagnostic laboratory test LCDs that would apply to all new clinical diagnostic laboratory test draft LCDs issued on or after January 1, 2015. The proposed process mirrors the current LCD process with the following modifications: (1) the public comment period would be shortened to a minimum of 30 days; (2) the Carrier Advisory Committee (CAC) meeting would be optional, at the discretion of the MAC, and there would be no public comment period; (3) the MAC would publish the final LCD 45 days after the close of the public comment period; and (4) the LCD would become effective immediately upon the date of publication.

Pfizer does not support CMS' proposal to refine the LCD process for clinical diagnostic laboratory tests by shortening the public comment period by 15 days and removing the public meeting requirement. This would reduce the transparency of the process and curtail the opportunity for stakeholder public comment and input. Pfizer strongly encourages CMS to reconsider this proposal as public input and process transparency are essential to the local coverage determination process. Moreover, we are concerned that changes to the LCD process for a sub-set of technologies could set a precedent to limit the public input process for other technology decisions.

4. Do not support proposed revisions regarding Sunshine Act regulations

CMS states that the exclusion for payments[2] related to continuing medical education ("CME") is "redundant with the exclusion in [42 C.F.R.] § 403.904(i)(1)." 79 Fed. Reg. at 40,384. The proposed revision excluding CME-related payments conditions this exclusion upon (1) the payment being for an event accredited by one of five specific organizations, (2) the applicable manufacturer not directly paying a speaker, and (3) the applicable manufacturer not influencing speaker selection. 42 C.F.R. § 403.904(g)(1). Knowledge of the recipient's identity is irrelevant. In contrast, § 403.904(i)(1) excludes payments only when the applicable manufacturer remains unaware of the recipient's identity through the end of the second quarter following the reporting year. Under § 403.904(i)(1), knowledge of the recipient's identity is the only fact that matters. Because the essential facts under § 403.904(g)(1) and § 403.904(i)(1) differ, they are not redundant.

The effect of removing the CME exclusion also shows that it is not redundant. Through the many CME advertisements it receives, or during a post-CME budget reconciliation, an applicable manufacturer is likely to learn who spoke (and therefore who was paid) at a CME event, even though there was no knowledge or direction given at the time funds were provided. With the CME exclusion in place, the applicable manufacturer's payment remains excluded, despite potential discovery of a physician speaker's identity (so long as the applicable manufacturer's payment met the three conditions for the CME exclusion). Without that express exclusion, the applicable manufacturer's payment will become reportable, merely because the applicable manufacturer happened to learn who the recipient was.

Further, Pfizer believes that CMS' proposal will allow reported CME events to be misperceived as subject to industry control, when in fact none existed. Some may perceive these programs as promotional in nature, even though they were actually independent of any industry influence. Such potential misperceptions contradict CMS' understanding that support of accredited or certified CME should be treated differently than other industry grants.

CMS also states that removing the CME exclusion will eliminate what some assert is "endorsement or support" of the five organizations identified in the CME exclusion. Nowhere in the preamble to the Sunshine Act regulation does CMS expressly endorse or support any accrediting organization. But even if the CME exception were an endorsement of an organization, removing the exclusion is no solution. Pfizer's experience indicates that CMS' burden estimate of one hour greatly underestimates the true burden that removing the CME exclusion would impose. Moreover, CMS would contradict its own conclusion that payments are not reportable when the applicable manufacturer conveys "full discretion" over speaker selection to the CME provider. 78 Fed. Reg. at 9492.

CMS' alternatives also are not viable solutions. Articulating accreditation or certification standards that allow a CME program to qualify for exclusion does not provide a timely solution because (1) CMS would need to promulgate additional rules and (2) depending on the language CMS proposes, those standards may not provide the bright-line

[2] Pfizer means "payments" to include "transfers-of-value."

guidance the current exclusion has. The other alternative—adding to the list of certified CME providers—does not allay the concern that CMS is endorsing or supporting specific CME providers.

Given the consequences of CMS' proposed and contemplated changes to the CME exclusion, Pfizer asks CMS to retain it as is. If CMS nonetheless feels compelled to change the exclusion, Pfizer suggests:

- eliminating the first condition in the exclusion (that "[t]he event at which the covered recipient is speaking must meet the accreditation or certification requirements and standards for continuing education for one of [five specific] organizations"); and
- retaining the other two conditions (that the applicable manufacturer neither directly pays the speaker nor influences speaker selection).

Removing the first condition eliminates any complaint that CMS endorses certain CME providers, but still obligates applicable manufacturers to convey full discretion over speaker selection to CME providers if they want the payment to be excluded. Conditioning the exclusion for CME-related payments on lack of influence over speaker selection is consistent with FDA and OIG guidance on best practices for industry support of CME.[3] Moreover, it will ensure that payment disclosure reflects how the industry is regulated and how it interacts with third-party organizations. Additionally, Pfizer's recommendation ensures that independent grants for CME will be treated equally, without a few that arbitrarily fall in scope for reporting thus creating an impression that industry controls these events.

CMS should not obligate applicable manufacturers to report the marketed name of non-covered products[4] nor prevent applicable manufacturers from associating multiple products with a single payment.

CMS intends to expand 42 C.F.R. § 403.904(c)(8) to require applicable manufacturers to report the marketed name of non-covered products related to reportable payments. 79 Fed. Reg. at 40,384. Less than two years ago, CMS refused the same expansion, explaining: "[W]e do not believe applicable manufacturers should be required to report the name of associated non-covered products, since this may be misleading to consumers and would provide information that is beyond the goal of the statute." 78 Fed. Reg. at 9474 (emphasis added). CMS has offered no explanation for abandoning its previous conclusion, and Pfizer is not aware of any justification for doing so. In any event, CMS cannot currently proceed with its proposed revision to § 403.904(c)(8) without estimating the substantial burden that its expanded collection of data will impose on applicable manufacturers.

Moreover, CMS should not implement its proposed revision of § 403.904(c)(8) because the proposal's language will force applicable manufacturers to report inaccurate data. Section 403.904(c)(8) currently allows applicable manufacturers to associate up to five products with a particular payment. That section further explains that "[if] the payment

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[3] FDA Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,903 (Dec. 3, 1997); HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).

[4] "Products" refers to drugs, devices, biologicals, and medical supplies

. . . was related to more than five covered [products], the applicable manufacturer should report the five covered [products] that were most closely related to the payment or other transfer of value." Id. CMS' proposal removes this option and accompanying guidance. 79 Fed. Reg. at 40,532. Instead, the proposed regulation directs applicable manufacturers to associate a single product with a payment. Id. Removing applicable manufacturers' ability to associate up to five products with a payment ignores how physicians and the industry interact. As CMS previously correctly observed, "many financial relationships are not specific to one product only." 78 Fed. Reg. at 9474. Therefore, CMS' proposed revision to § 403.904(c)(8) will prevent applicable manufacturers from accurately reporting some of their interactions with physicians. If CMS is going to revise section 403.904(c)(8), Pfizer asks CMS to retain section 403.904(c)(8)'s option to associate up to five products and its guidance about how to choose which products to associate.

5. Changes to Measure Sets and Suggested Areas for Inclusion in PQRS Related to Quality Measures

The Proposed Rule describes several proposals to continue expansion of reporting on quality measures under the PQRS. Our comments on some of the specific proposals follow.

Tobacco Use and Help With Quitting Among Adolescents

Pfizer strongly supports CMS' inclusion of the measure "*Tobacco Use and Help With Quitting Among Adolescents*" in the PQRS measure set. Smoking remains a major public health issue in the United States. Despite a decline in smoking rates over the past four decades, data indicate that these rates have stalled significantly in recent years; approximately 42.1 million Americans continue to smoke.[5] Cigarette smoking remains the most preventable cause of premature death in the U.S. and accounts for nearly 480,000 deaths annually.[6] As such, there remains a strong need to incentivize physicians to assess patients for tobacco use and improve rates of smoking cessation. This is true particularly among adolescents, as 9 out of 10 smokers are estimated to having started smoking by age 18, making this a important age group on which to focus smoking cessation efforts.

Pain Measures

Pfizer supports CMS' proposed removal of the measures "Back Pain: Initial Visit" and "Back Pain: Physical Exam" from the PQRS measure set. Pfizer commends CMS for reevaluating the need for measures that assess commonplace clinical processes and encourages CMS to consider additional pain process and outcomes measures that will have a greater impact on improved care quality. With that goal in mind, Pfizer supports CMS' proposed inclusion of the measure "**Median Time to Pain Management for Long**

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[5] Centers for Disease Control and Prevention. "Current Cigarette Smoking Among Adults — United States, 2005-2012." Morbidity and Mortality Weekly Report. 17 January 2104. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6144a2.htm. Accessed July 25, 2014.

[6] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Accessed July 25, 2014.

Bone Fracture" and encourages CMS to consider additional pain assessment measures in PQRS.

According to national practice guidelines and systematic reviews of pain management research, a thorough, comprehensive pain assessment is required for informed clinical decision making and appropriate pain intervention.[7,8,9,10] As such, Pfizer recommends the National Quality Forum (NQF) endorsed pain-related measure "**Patients with Advanced Cancer Screened for Pain at Outpatient Visits"** for use in the PQRS program. This measure assesses whether adults with advanced cancer are screened for pain with a standardized quantitative tool at each outpatient visit. The inclusion of additional pain measures in PQRS will further ensure optimal, high quality care for those patients experiencing pain.

Oncology Measures

Pfizer supports CMS' inclusion of the measures **"Lung Cancer Reporting (Biopsy/Cytology Specimens)," "Lung Cancer: Reporting (Resection Specimens)," and "Melanoma Reporting."** These measures fill important gaps in oncology care. Patients diagnosed with cancer are frequently treated by multiple providers. The introduction of these measures will help improve overall care coordination and provider communications and help ensure patients receive timely and efficient care.

Urinary Incontinence Measures

Urinary incontinence is a high-burden condition, with an estimated 25 million adults experiencing temporary or chronic urinary incontinence.[11] Pfizer encourages CMS to expand the number of urinary incontinence quality measures to the PQRS program. This is an important area that is not adequately addressed by current measurement programs, and these measures are integral to improving patient outcomes and ensuring best practices for optimal care delivery to Medicare beneficiaries.

Given these concerns, while Pfizer generally supports the removal of measures that have received regular performance at or near 100 percent of reporting eligible providers ("topped-out" measures), we encourage CMS to consider refraining from removing topped out measures such as "**Urinary Incontinence: Characterization of Urinary Incontinence in Woman Aged 65 years and Older**" from pay-for-reporting programs. In the proposed methodology for determining whether a measure has reached topped out status, only the measure reporting rate is considered. The removal of these topped out measures may prevent the assessment of providers' ability to not

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[7] Wisconsin Medical Society Task Force on Pain Management. "Guidelines for the assessment and management of chronic pain." *WMJ*. 2004;103(3):13-42.
[8] American Geriatric Society (AGS). "The management of persistent pain in older persons." *J Am Geriatr Soc*. Jun 2002;50(6 Suppl):S205-224.
[9] Hadjistavropoulos T, Herr K, Turk DC, et al. " An interdisciplinary expert consensus statement on assessment of pain in older persons." *Clin J Pain*. Jan 2007;23(1 Suppl):S1-43.
[10] Institute for Clinical Systems Improvement. "Assessment and management of chronic pain." Bloomington, MN; 2007.
[11] National Association for Continence. "Facts & Statistics." http://www.nafc.org/index.php?page=facts-statistics. Accessed July 25, 2014.

only report on these measures, but to improve patient outcomes. This is particularly problematic when considering a high-burden condition such as urinary incontinence.

Pfizer also encourages CMS to consider additional measures assessing care for urinary incontinence for PQRS. At this time, there are four NQF-endorsed measures assessing the care provided to those patients with urinary incontinence, three of which are already included in PQRS. CMS may consider incorporating the following measure into the PQRS program:

- **Urinary Incontinence Management in Older Adults**: a. Discussing urinary incontinence, b. Receiving urinary incontinence treatment (NQF #0030) – Percentage of patients 65 years of age and older who reported having a urine leakage problem in the last six months and who discussed their urinary leakage problem with their current practitioner

The inclusion of this measure will help ensure optimal, high quality care for patients with urinary incontinence and is of particular relevance for the Medicare population.

Chronic Obstructive Pulmonary Disease

While Pfizer appreciates CMS' rationale for removing the measures "**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation" and "Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy"** from PQRS as the measure steward will no longer be maintaining these measures, the removal of these measures would create a significant measurement gap in PQRS. These are the only COPD measures included in PQRS and Pfizer encourages CMS to assume stewardship responsibilities of these measures or identify a measure contractor for ongoing measure maintenance, at least until such time as appropriate replacement measures can be identified.

Stroke Rehabilitation Measures

Pfizer encourages CMS to postpone removal of "**Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy" and "Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge**" from PQRS. In their rationale CMS states that the measures are proposed for removal as they represent "a clinical concept that is currently included within inpatient standard of care." However, in the FY 2015 Inpatient Prospective Payment System, CMS has proposed to retire these measures as they have reached topped out status in IQR. We encourage CMS to postpone removal of these measures until it can be determined whether they will remain in the inpatient setting.

Perioperative Care: VTE Prophylaxis (When Indicated in ALL Patients)

Pfizer encourages CMS to consider additional measures assessing the care of patients with VTE to replace this measure. VTE is estimated to have an incidence rate of 1 per 1,000 patients[12] and be the third most prevalent cardiovascular disease.[13,14] There are

[12] Amin A, Stemkowski S, et al. Thromboprophylaxis rates in US medical centers: success or failure? J Thromb Haemost. 2007;5:1610-6.

several aspects of care such as primary stroke prevention and secondary prevention of subsequent VTE that are not currently addressed in PQRS that Pfizer suggests CMS consider as priorities for measure development and adoption.

6. Establishment of New Cross-Cutting Individual Measures

Under the Proposed Rule, satisfactory reporting under the PQRS would require some EPs to report on one or more cross-cutting measures. CMS proposes to include 18 new cross-cutting measures for 2015 and beyond.

Pfizer strongly supports CMS' decision to establish a list of individual cross-cutting measures and requirements for provider reporting. Establishing core standards for treatment regardless of the patient's condition or the provider specialty is essential to ensuring overall quality of care improvement. Pfizer commends CMS for the inclusion of multiple measures addressing care coordination, and supports the appropriate identification of targeted clinical measures that are applicable across multiple conditions and therapeutic areas, such as tobacco cessation, pneumococcal immunization, and pain assessment. Pfizer encourages CMS to continuously review the measures considered as cross-cutting and add new measures as appropriate for the Medicare population.

7. **Expansion of the VBPM**

The "Value-Based Payment Modifier" (VBPM) is the mechanism required by the Affordable Care Act that eventually (by 2017) will convert the physician fee schedule payment system into a "value-based" system reflecting physicians' performance on certain quality and cost metrics. The proposed rule would continue phasing in the modifier, by expanding the number of physician practices affected by the modifier and the percentage of payments at risk for 2017.

Beginning January 1, 2015, the Medicare payment for items and services billed by physicians in groups of 100 or more eligible professionals will generally be subject to the modifier; however, CMS will not apply the VBPM to any physician group participating in the Medicare Shared Savings Program, the Pioneer ACO model, or the Comprehensive Primary Care Initiative or similar Innovation Center initiatives until 2017.

Beginning in 2017, CMS would increase the amount of risk associated with the VBPM to 4%, and would apply the VBPM to physician and non-physician eligible professionals in groups with 2 or more eligible professionals, and to solo practitioners (both physician and non-physician). Under the new rule, non-physician eligible professionals would receive the same treatment and be subject to the same amount of payment risk and quality-tiering policies as physicians.

Last year, CMS finalized inclusion of a claims-based measure, Medicare Spending per Beneficiary, within the cost domain for all attributed beneficiaries, in addition to the

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[13] Ibid.

[14] Heit JA, O'Fallon WM, et al. Relative impact of risk factors for deep vein thrombosis and pulmonary embolism: a population-based study. Arch Intern Med. 2002;162:1245-8.

Total per Capita Costs measure and Total per Capita Costs for beneficiaries with four conditions: Chronic Obstructive Pulmonary Disease, Coronary Artery Disease, Heart Failure, and Diabetes measures. While resource use measures, like these, report information about costs of treatment, they do not provide any information about the quality of care provided relative to those costs, and therefore do not represent efficiency or accurately demonstrate value. It is important to report appropriate quality data alongside any cost data, and ensure that the quality data have a meaningful relationship to cost data, as a framework for interpretation so that the cost data are not misused or misunderstood. While the value-based payment modifier (VM) has a quality component consisting of quality measures and eligible professional reports through PQRS, the quality of care evaluated may not relate to the costs calculated.

Well-designed quality measures, preferably outcomes measures, can help to balance cost measures and ensure that patients are receiving the right types of treatment to achieve desired health outcomes, if those quality measures relate to the cost measures. We are concerned that application of unbalanced cost measures could result in reduced provision of needed care and decreased beneficiary access to medically beneficial treatments in an effort to stem costs, especially when applied in an incentive program. Therefore, we encourage CMS to investigate alternative frameworks for true efficiency measurement that would allow for the proper tandem evaluation of cost and quality.

Further, we note that the Total per Capita Costs measures are not NQF-endorsed, and the Medicare Spending per Beneficiary measure is not endorsed at the physician or group level. Many concerns were raised by the members of the NQF Cost and Resource Use Steering Committee charged with reviewing these measures. The reliability and validity of these measures was questioned and challenged. For the purpose of the VM program, we understand that, by statute, CMS is required to incorporate cost measures. In meeting this statutory requirement but recognizing the validity and reliability issues with these measures, we suggest that CMS may weight more heavily the quality measures used in the VM so that the quality tiering of physician groups is defined based more upon the quality of care being rendered.

Pfizer supports CMS' proposals to expand the use of the VBPM to include more providers and provider types, and we encourage CMS to ensure that there are adequate quality measures for non-physician eligible professionals to report on as part of these requirements.

Pfizer supports CMS' proposal to include an upward payment adjustment for providers participating in an accountable care initiative to care for high-risk beneficiaries. High-risk beneficiaries may require additional care coordination activities and treatment management that can result in additional risk and associated costs for providers. This proposal recognizes the critical activities undertaken by providers when caring for high-risk beneficiaries and encourages providers to focus on the unique needs of this patient population.

8. Proposed Quality Measure Changes to MSSP

Pfizer supports CMS' proposal to add the measure "All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (addition)" to the Medicare Shared Savings Program (MSSP). Individuals with multiple chronic conditions (MCCs) comprise just

over 25 percent of the U.S. population, many of whom are Medicare beneficiaries. Patients with MCCs have their own unique treatment considerations which may include additional complications and care by multiple providers. Therefore, Pfizer encourages CMS to continue to consider measures that assess the unique needs of this population and ensure that high quality care is provided, particularly given the likelihood of treatment by multiple providers. MSSP and the accountable care model represents an ideal setting to hold providers accountable to the holistic needs of these patients as the program is designed to promote effective care coordination and communication.

Pfizer encourages CMS to reconsider the removal of the measure "Diabetes Mellitus: Tobacco Non Use." While CMS states that this measure is duplicative of the measure "Tobacco Screening and Cessation Counseling" already found in the program, the outcome measure "Diabetes Mellitus: Tobacco Non Use" has very different requirements from the process measure "Tobacco Screening and Cessation Counseling" and holds provider smoking cessation efforts with patients to a much higher standard for success. Pfizer therefore encourages CMS to refrain from removing this measure in an effort to continue to support smoking cessation activities.

In addition to the measures already proposed for inclusion in MSSP, Pfizer suggests CMS consider measures to fill the following measurement gaps: medication adherence, pain, and bladder control.

Pfizer encourages CMS to promote medication adherence through the use of existing, NQF-endorsed medication adherence measures. This could be a low-burden, but high-value approach to quality performance assessment.

In addition, the important clinical area of pain is not included and should be considered as part of quality measurement under the MSSP. Among the NQF-endorsed measures, there are a number that could be considered:

- Pain Assessment and Follow-Up (PQRS 2014, NQF #0420) - Percentage of patients aged 18 years and older with documentation of a pain assessment (if pain is present, including location, intensity, and description) through discussion with the patient including the use of a standardized tool on each qualifying visit prior to initiation of therapy AND documentation of a follow-up plan.
- Care for Older Adults (COA) (HEDIS 2014) - Percentage of adults 65 and older who had each of the following during the measurement year: advance care planning; functional status assessment; medication review; and pain screening.
- Osteoarthritis: functional and pain assessment (PQRS 2014) - Percentage of patients with osteoarthritis who were assessed for function and pain.
- Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy (PQRS 2014, NQF #0054) - Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a DMARD.

In addition, Pfizer encourages the inclusion of the CMS Medicare Advantage Star Rating Measure on Bladder Control, which measures the percentage of members with a urine leakage problem who discussed the problem with their doctor and received treatment for it within six months.

Conclusion

Pfizer appreciates the opportunity to comment on the Medicare Physician Fee Schedule CY 2015 proposed rule. We appreciate CMS' willingness to collaborate with all healthcare stakeholders, including the life sciences industry, to improve the health of the Medicare population.

We welcome further discussion on the direction and focus of this proposed rule and we look forward to working with CMS to improve care delivery and ensure continued access to high-quality care.

Sincerely,

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